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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K023712

1. Date of summary: October 30, 2002

2. Submitted by: Advantage Diagnostics Corporation
764 San Aleso Avenue
Sunnyvale, CA 94085

3. Device Name: Advantage Multiple Drugs of Abuse Test.

4. Device Classification: CFR 21 862.3870, 862.3650, 862.3250, 8610.3610, Class II, Panel 91 Toxicology

5. Device description: The Advantage Multiple Drugs of Abuse Test is an immunochromatographic based one step *in vitro* test.

6. Intended Use: The Advantage Multiple Drugs of Abuse Test is a qualitative, one step immunochromatographic competitive assay used to screen human urine for the presence of the six commonly abused drugs at cut off concentrations of 50 ng/mL THC, 300ng/mL benzoylecgonine/cocaine, 2,000ng/mL opiates, 1,000ng/mL methamphetamine 1,000ng/mL amphetamine and 25ng/mLPCP. The tests are formatted in a multiple plastic card, which holds up to 5 drug test strips, and a single plastic test card, which holds a single drug test strip. The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS.

7. Substantial Equivalence: The Advantage Multiple Drugs of Abuse Test was found substantially equivalent to GC/MS and EMIT testing. The individual Advantage drug tests demonstrated correlations between 90-96% as compared to GC/MS and >99% in drug free urine as compared to EMIT testing.

Conclusion:
The Advantage Multiple Drugs of Abuse Test is substantially equivalent in performance characteristics to GC/MS testing and EMIT testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Janis Freestone
Director, Regulatory Affairs
Advantage Diagnostics Corporation
764 San Aleso Avenue
Sunnyvale, CA 94085

JAN 31 2003

Re: k023712
Trade/Device Name: Advantage Multiple Drugs of Abuse Test
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ; LDJ; DIO; DJC; DJG; LCM
Dated: January 7, 2003
Received: January 9, 2003

Dear Ms. Freestone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510k Number:

Device Name:
Advantage Multiple Drugs of Abuse Test

Indications for Use:

The Advantage Multiple Drugs of Abuse Test is a qualitative, one step, immunochromatographic competitive assay used to screen human urine for the presence of one to five of the following Drugs of Abuse at the indicated cut off: THC 50ng/mL, Phencyclidine (PCP) 25ng/mL, Opiates 2000 ng/mL, Cocaine 300ng/mL, Amphetamine 1,000ng/mL and Methamphetamine 1,000ng/mL. The tests are formatted in multiple plastic test cards, which hold up to 5 drug test strips, and single plastic test cards which hold one drug test strip. The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS. The test is for professional use.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023712

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the counter use_____
(Per 21 CFR 801.109)